UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MARC PETERS-GOLDEN and THEODORE STANDIFORD

Appeal 2007-1145
Application 09/291,656
Technology Center 1600

Decided: May 30, 2007

Before ERIC GRIMES, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a solution for treating a microbial infection. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part, vacate-in-part, and enter a new ground of rejection.

BACKGROUND

The Specification describes treating "patients with a recognized predisposing factor . . . for overwhelming pneumonia, or with early

pneumonia, with administration via inhalation or an endotracheal tube of metabolic products of the 5-lipoxygenase pathway (*e.g.*, leukotrienes)" (Specification 4). These products may also be administered for the treatment and prevention of other conditions, such as other microbial infections (*id.* at 4-5), "may be administered concomitantly with antibiotics" (*id.* at 5), and may be administered through a bronchoscope (*id.* at 22).

The Specification also describes "a solution for the treatment of a microbial infection . . . comprising a sterile liquid vehicle and a leukotriene dissolved in the sterile liquid vehicle" (*id.* at 6). The solution may be aerosolized (*id.*).

DISCUSSION

1. CLAIMS

Claims 22-25 and 27-37 are pending and on appeal. Claims 22, 28, and 33 are representative and read as follows:

> 22. A solution for the treatment of a microbial infection, said solution comprising a sterile liquid vehicle, an antibiotic and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is an aerosol.
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> 28. A solution for the treatment of a microbial infection, said solution comprising a sterile liquid vehicle, an antibiotic and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is in an intratracheal instillation device, said instillation device is selected from the group consisting of an endotracheal tube and a bronchoscope.
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> 33. A composition for the treatment of a microbial infection comprising, a sterile liquid vehicle, an antibiotic and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is contained within a nebulizer.

Claim 22 is directed to a solution comprising an antibiotic and a leukotriene dissolved in a sterile liquid vehicle. Claim 22 also includes a "wherein" clause stating that the solution is an aerosol. Appellants assert that the term "aerosol" is defined as a "gaseous suspension of fine solid or liquid particles" or as a substance "packaged under pressure with a gaseous propellant for release as a spray of fine particles" (Reply Br. 2). The Examiner has interpreted the claim to give the "wherein" clause no patentable weight (Answer 3).

We disagree with the Examiner's claim interpretation. During prosecution, claims are given their broadest reasonable interpretation. *In re Sneed*, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983). Here, the Specification states that a "preferred mode of administration comprises administration to the lung. . . . [I]ntrapulmonary delivery of pharmacologic agents to patients not requiring mechanical ventilation can be accomplished via aerosolization" (Spec. 22: 12-16).

The Specification's description of administering compositions by aerosolization supports Appellants' position that claim 22 defines a composition in aerosol form or in a form suitable for aerosolization (corresponding to Appellants' two definitions of "aerosol"). The Examiner has not disputed the accuracy of Appellants' definitions of "aerosol." We therefore interpret claim 22 to be directed to a composition comprising the recited elements, in a form which is either a gaseous suspension of particles or packaged under pressure with a gaseous propellant.

Claims 28 and 33 are each directed to the same solution[1] recited in claim 22, and include "wherein" clauses stating that the solution is in an endotracheal tube or a bronchoscope (claim 28), or in a nebulizer (claim 33). We will address the interpretation of claims 28 and 33 infra.

2. REFERENCES

The Examiner relies on the following reference:

Gosselin US 5,789,441 Aug. 4, 1998.

The Examiner also relies on U.S. Application No. 08/602,059 (hereinafter the '059 Application), filed February 15, 1996, a copy of which was made of record in the present Application by Appellants. Gosselin claims the benefit of priority based on the '059 Application.

3. CLAIMS 22-25 AND 27

Claims 22-25 and 27 stand rejected under 35 U.S.C. § 103 as obvious over Gosselin. The Examiner relies on Gosselin for teaching "leukotriene LTB_4 in a sterile liquid (cols. 11-13 and Example I, col. 14, lines 15-16, for example)" (Answer 2). The Examiner argues that "support for sterile solutions of leukotrienes can be found in the Examples [of the '059 Application] at pages 13-15" (*id.* at 3-4). Specifically, the Examiner argues that "Gosselin et al. were in possession of sterile solutions of leukotrienes because they used these solutions in cell culture AND kept the cell culture

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[1] Claim 33 actually recites a "composition for the treatment of a microbial infection." Claim 33 also refers to "said solution," which creates an issue of antecedent basis since there is no earlier reference in claim 33 to a solution. For the purpose of this appeal, we are assuming that "said solution" refers back to the "composition." However, if prosecution of this application is continued, the antecedent basis issue in claim 33 should be resolved.

alive for at least seven days, indicating that the experiment was not 'quick and dirty' but intended to be performed under aseptic techniques" (*id.* at 4).

In addition, the Examiner argues that Gosselin "states that the invention provides for the use of an LTB_4 agent as a therapeutic against Gram + and – infections, or fungal infections alone or in association with other antibacterial or antifungal agents" (Answer 2-3, citing Gosselin, col. 5, ll. 24-29; see also Answer 4, citing '059 application 8) and that therefore "it would have been obvious to a person having ordinary skill in the art to include an antibiotic in a solution comprising a sterile liquid and a leukotriene" (Answer 3).

The Examiner gives the recitation that the solution is "aerosolized . . . no patentable weight" (*id.*). The Examiner also argues that the "aerosol" limitation does not distinguish the claimed solution from that of Gosselin because "each droplet within an aerosol is the sterile solution of leukotriene taught in the Gosselin et al. patent and parent. Therefore, whether one has a beaker of the solution of sterile leukotriene or a droplet of the solution of sterile leukotriene, the solution is not discernible. . . . Also, 'aerosol' describes a dosage form, not the solution itself." (*Id.* at 5.)

Although we disagree with the Examiner's interpretation of claim 22, we agree with her that the claimed solution would have been obvious in view of Gosselin. Gosselin describes the use of "leukotriene B4 (LTB_4) agent as an antiviral agent" (Gosselin, col. 4, ll. 30-31; '059 Application 6). In addition, Gosselin describes the use of LTB_4 as a "therapeutic agent against bacterial Gram + and – infections or fungal infections, alone or in association with other antibacterial or antifungal agents" (Gosselin, col. 5,

ll. 24-29; '059 Application 8). "LTB_4 agent" refers to LTB_4 itself or to analogs, precursors, or metabolites of LTB_4 (Gosselin, col. 6, ll. 16-29; '059 Application 9). Based on the teachings of Gosselin that are supported by the '059 Application, we conclude that it would have been obvious to include both LTB_4 and an antibiotic in a composition for treating bacterial infections.

To administer the LTB_4, the Examples describe the use of nanomolar solutions of LTB_4; i.e., compositions of LTB_4 in a liquid vehicle (Gosselin, col. 14, ll. 15-16 and col. 18, ll. 51-52; '059 Application 13 and 15). Although the '059 Application does not specifically recite that the liquid vehicle is sterile, we agree with the Examiner that using a sterile liquid vehicle for a therapeutic solution would have been obvious. *Cf. KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1739, 82 USPQ2d 1385, 1395 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Appellants argue that Gosselin is not properly cited prior art because the application that resulted in Gosselin was filed after the effective filing date of Appellants' application (Br. 7).

We are not persuaded by this argument. The present application claims an effective filing date of December 3, 1996. The Application that issued as Gosselin was filed after December 3, 1996, but claims the benefit of the '059 Application, which was filed February 15, 1996. Thus, Gosselin appears to be prior art under 35 U.S.C. § 102(e) as to any subject matter described in Gosselin that is supported by the '059 Application.

The disclosures of Gosselin that support a prima facie case of obviousness are also found in the '059 Application. Therefore, Gosselin is available as prior art, at least in relevant part, under 35 U.S.C. § 102(e).

Appellants also argue that Gosselin "does not teach a leukotriene/antibiotic combination" and that the '059 Application does not teach a sterile liquid (Br. 10-11). For the reasons discussed above, we are not persuaded by these arguments.

Appellants also argue that the '059 Application does not teach "an aerosol" (Br. 7, 10) and that "[b]ecause 'an aerosol' is not functional language the Examiner MUST give this claim element full patentable weight" (*id.* at 8). In particular, Appellants argue that "an aerosol is a composition of matter within its own right" (Reply Br. 3).

While we agree with Appellants that claim 22's "wherein" clause limits the claim to a solution in the form of an aerosol, we do not agree that that limitation distinguishes the claimed solution from that of Gosselin. Appellants define an "aerosol" as a solution in one of two forms: "a gaseous suspension of fine solid or liquid particles" or a "substance . . . packaged under pressure with a gaseous propellant for release as a spray of fine particles" (Reply Br. 2).

Gosselin does not disclose a solution in the form of a gaseous suspension or under pressure with a gaseous propellant. However, a solution is not changed by the composition of the gas overlying it or the pressure of that gas. A solution comprising a leukotriene, an antibiotic, and a sterile liquid vehicle is the same solution regardless of whether the solution is in an open container (i.e., under air at atmospheric pressure) or whether it is

"packaged under pressure with a gaseous propellant." Thus, claim 22's limitation that the "solution is an aerosol" does not distinguish the claimed solution from the solution disclosed by Gosselin and the '059 Application.

We affirm the rejection of claim 22. Claims 23-25 and 27 were not separately argued and fall with claim 22. 37 C.F.R. § 41.37(c)(1)(vii). Since our reasoning differs from that of the Examiner, however, we designate our affirmance as a new ground of rejection under 37 C.F.R. § 41.50(b) in order to give Appellants a fair opportunity to respond.

4. CLAIMS 28-37

Claims 28-37 also stand rejected under 35 U.S.C. § 103 as obvious over Gosselin. The Examiner's rationale is the same as with respect to claim 22 – the "wherein" clauses of claims 28 and 33 are not claim limitations and Gosselin would have suggested a solution comprising a leukotriene, an antibiotic, and a sterile liquid vehicle (Answer 3).

Appellants argue that the "wherein" clauses of claims 28 and 33 are claim limitations, and the recited limitations are not suggested by Gosselin (Br. 10-11).

We conclude that both the Examiner's and Appellants' claim interpretations are reasonable. The Examiner correctly points out that the claims are directed to "solution[s]," which are compositions of matter that are the same no matter what they are contained in (Answer 3). At the same time, Appellants correctly argue that the "wherein" clauses of claims 28 and 33 impose structural, not functional, requirements and therefore could further limit the claims (Br. 8).

Like a "whereby" clause, whether a "wherein" clause is a claim limitation depends on the facts of a particular case. *Compare Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005) ("whereby" clause held to limit claim scope) with *Minton v. National Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("whereby" clause held not to limit claim scope).

Here, it is unclear whether claims 28-37 are directed to a composition (such that the wherein clauses are not entitled to weight) or to a manufacture (such that the wherein clauses are entitled to weight). Because we cannot tell what is required by the claim language, we cannot tell whether what is claimed would have been obvious in view of Gosselin. We therefore vacate the § 103 rejection and enter a new rejection for indefiniteness.

NEW GROUND OF REJECTION

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection: Claims 28-37 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

As discussed above, claims 28 and 33 are susceptible to two reasonable interpretations. The scope of these claims is therefore unclear. "[A]mbiguity in claim scope is at the heart of the definiteness requirement of 35 U.S.C. § 112, ¶ 2." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342, 65 USPQ2d 1385, 1406 (Fed. Cir. 2003). "A claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention." *Id.*

In addition, a claim purportedly directed to more than one statutory class of invention is indefinite because it is unclear what would constitute

infringement of the claim. *Cf. Ex parte Lyell*, 17 USPQ2d 1548, 1551 (Bd. Pat. App. Int. 1990) ("[A] single claim which purports to be both a product or machine and a process is ambiguous and is properly rejected under 35 USC 112, second paragraph, for failing to particularly point out and distinctly claim the invention."); *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 77 USPQ2d 1140 (Fed. Cir. 2005) (A single claim covering both an apparatus and a method of using that apparatus is indefinite because it is unclear what acts constitute infringement of the claim).

Here, it is unclear whether claims 28 and 33 are directed to a "solution," as recited in the preamble, or whether infringement would require use or sale of the combination of a solution and a nebulizer or endotracheal tube. We decline to try to harmonize the preamble and "wherein" clauses of claims 28 and 33. If Appellants intend to claim an article of manufacture that comprises a solution and a nebulizer or endotracheal tube, they can amend the claims to clearly recite that: "It is the applicants' burden to precisely define the invention, not the PTO's. See 35 U.S.C. § 112, ¶ 2. . . . [T]his section puts the burden of precise claim drafting squarely on the applicant." *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1029 (Fed. Cir. 1997).

If the claims are amended so that they clearly claim an article of manufacture, any rejection would of course need to address the limitation reciting the nebulizer, endotracheal tube, etc. containing the solution.

Claims 29-32 and 34-37 depend on claims 28 and 33, respectively, and are indefinite for the same reason.

SUMMARY

We affirm the examiner's rejection of claims 22-25 and 27. Since our reasoning differs somewhat from that of the examiner, however, we designate our affirmance a new ground of rejection under 37 C.F.R. § 41.50(b). We vacate the rejection of claims 28-37 and enter a new ground of rejection for indefiniteness. Appellants' options for responding to a new ground of rejection (see below) apply to both rejections.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

AFFIRMED-IN-PART

37 C.F.R. § 41.50.(b)

smsc

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